Invited commentaries

Patient safety is an important problem in the USA today. The 1999 Institute of Medicine (IOM) report, *To Err Is Human*, brought the issue into the public eye (1). This report suggested that 44,000 to 98,000 patients die annually in the USA as a result of medical errors and that approximately a million patients are injured. These figures seemed implausible to many and have been the object of considerable controversy (2–4), but most agree that whatever the true figures are they are higher than would be desirable.

Before the IOM report, the problem of patient safety was not visible on the radar screen of most of the nation's health care leaders or providers; in a 1999 Advisory Board survey, hospital chief executive officers ranked "reducing clinical errors and adverse events" 133rd on their priority list. A major reason for this lack of visibility is that health care organizations use primarily spontaneous reporting to detect errors and adverse events, and spontaneous reporting detects only a minority of adverse events. The proportion is about 1 in 20 for adverse drug events (5), and for medication errors the figure is much lower (6). At Brigham and Women's Hospital, we have estimated that we have about 300,000 medication errors annually (many of these have little or no potential for harm), yet only a few hundred are reported. For patient safety to improve, this issue has to be higher on the leadership's list. Clearly, Baylor's leadership has become engaged, as demonstrated by Mr. Hood's commentary in this issue of *BUMC Proceedings*.

For adverse events, a number of promising approaches are being used and refined that should make detection easier (7, 8). Typically, these rely on using computerized data to identify "signals" that suggest that an adverse event may have occurred. Such tools may allow routine assessment of the frequency of adverse events and could even provide sufficiently robust information to allow benchmarking. In contrast, benchmarking with spontaneous reporting is probably not meaningful, except internally, since higher rates are probably actually better, and the reporting rate depends so much on the safety climate. Spontaneous reporting will remain useful for error detection, since computerized moni-

toring so far does not appear especially effective for detecting errors (8).

One issue is whether to focus on errors or adverse events. I believe that both are useful. Errors and near misses are important because they occur many times as often as adverse events (6). Thus, after a process change, it is easier to detect a change in the error rate than the adverse event rate. Aviation has dramatically improved safety largely by focusing on near misses. However, most errors have little or no potential for harm, though they may be costly to the system because of the extra work they cause. It is also important to track adverse events, because at the end of the day it is the adverse event rate that we seek to reduce to improve patient safety. Among errors that have the potential to hurt patients, errors that actually result in injuries appear to be different from those that do not (9). In particular, the errors that hurt patients tend to be subtler than those that could but get intercepted (for example, a 5-fold overdose may slip through when a 50-fold overdose would not).

Spontaneous reporting of errors and adverse events has yielded many useful lessons, especially at the national level. For anesthesia, neonatal intensive care units, and medication errors and adverse drug events, databases have been built, which have revealed important ways that care could be improved. For example, associations between Norplant (a contraceptive that can be implanted in the forearm) and a variety of complications including infections at the insertion site, hospitalizations because of difficulty removing the capsule, stroke, thrombotic thrombocytopenic purpura, thrombocytopenia, and pseudotumor cerebri were identified through the Food and Drug Administration's Medwatch program (10). Also, a number of deaths associated with concentrated potassium have been identified through the Medication Errors Reporting Program, and a series of warnings regarding these risks by the Institute for Safe Medication Practices (11) and others have resulted in removal of the medication from most units in the nation's hospitals.

Reporting is also important within organizations because it provides local information about problems, and leadership is

often skeptical regarding whether problems that present one place are actually occurring at another.

Yet getting clinicians to report has been challenging. Rates are often low—a third of organizations report having no medication errors. Strategies to increase reporting rates have often had little or no effect (5). Some groups of providers do most of the reporting (nurses and pharmacists)—and some groups, like physicians, almost never report. Clearly, new strategies to increase reporting rates are needed.

In this issue of the *BUMC Proceedings*, 2 articles describe the impact of novel Web-based reporting systems (see articles by J. F. Dixon et al and T. Atherton). Both applications resulted in a substantial increase in the number of reports of errors and adverse events. Compared with paper reporting, such tools have a number of important advantages: data can be coded as they are collected, anonymous reporting is facilitated, greater security can be achieved, data are more immediately available, analysis is vastly easier, and rates and types of reports can be compared with those of other organizations.

Another issue is whether organizations should build their own tool or use one that is externally developed. I believe that organizations using tools that have been developed elsewhere have substantial advantages. Specifically, using an externally developed tool promotes use of standardized definitions, allows comparisons within a network, facilitates building branching algorithms that can be done electronically but not with paper, and makes it easier to maintain and update the application. Furthermore, incident tracking works well as a stand-alone application that need not be closely integrated with the organization's underlying information system.

Getting more reports represents a key step in building a culture of safety, since being willing to report and having taken the risk of reporting may make individuals more invested. Growing a culture of safety in health care is challenging, especially since the traditional approach to dealing with errors is to find the responsible individuals and punish them. However, good people make most errors. A more productive approach may be to identify bad behavior and deal with that, instead of castigating those who make or report errors.

However, getting more reports is not an end in itself. Simply having the reports does not tell you what to do with them. They must be analyzed, which is not trivial. Assessing frequency and root causes using a human factors approach is essential, and the tools of failure mode and effects analysis are important. New techniques like data mining may be valuable for assessing previously unrecognized associations within databases. Organizations

need infrastructure to successfully perform these analyses and to make the changes that the analyses suggest. That requires having a director of patient safety within the organization, with a staff and budget. Too often, such work is delegated to someone with no dedicated time for it.

Thus, increased reporting represents the beginning on the road to a safer health care system, not the end. The key steps will be developing tools to analyze reports and other types of patient safety data, building the infrastructure within organizations to make processes safer, testing that these steps have made a difference, and monitoring them.

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1. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human. Building a Safer Health System*. Washington, DC: National Academy Press, 1999.
2. Brennan TA. The Institute of Medicine report on medical errors—could it do harm? *N Engl J Med* 2000;342:1123–1125.
3. Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA* 2000;284:95–97.
4. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA* 2000;284:93–95.
5. Cullen DJ, Bates DW, Small SD, Cooper JB, Nemeskal AR, Leape LL. The incident reporting system does not detect adverse drug events: a problem for quality improvement. *Jt Comm J Qual Improv* 1995;21:541–548.
6. Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape L. Relationship between medication errors and adverse drug events. *J Gen Intern Med* 1995;10:199–205.
7. Hripcsak G, Friedman C, Alderson PO, DuMouchel W, Johnson SB, Clayton PD. Unlocking clinical data from narrative reports: a study of natural language processing. *Ann Intern Med* 1995;122:681–688.
8. Honigman B, Lee J, Rothschild J, Light P, Pulling RM, Yu T, Bates DW. Using computerized data to identify adverse drug events in outpatients. *J Am Med Inform Assoc* 2001;8:254–266.
9. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, Laffel G, Sweitzer BJ, Shea BF, Hallisey R, Vander Vliet M, Nemeskal R, Leape LL. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA* 1995;274:29–34.
10. Wysowski DK, Green L. Serious adverse events in Norplant users reported to the Food and Drug Administration's MedWatch Spontaneous Reporting System. *Obstet Gynecol* 1995;85:538–542.
11. Institute for Safe Medication Practices. Despite knowledge of accidents, opportunities for potassium ADEs persist in some US hospitals. *ISMP Medication Safety Alert* 1996 (August 28). Available at <http://www.ismp.org/msaarticles/potassium.html>. Accessed February 12, 2002.

With the publication of the Institute of Medicine report *To Err Is Human* in 1999 (1), health care organizations throughout the country were challenged to improve patient safety and reduce medical errors. Reporting systems are one part of the patient safety equation.

In this issue of *BUMC Proceedings*, hospitals in the Baylor Health Care System describe their experiences with incident reporting systems, one developed internally (2) and one developed by a national vendor (DoctorQuality) (3). While sometimes

described as error reporting systems, they are both truly incident or event reporting systems, with only some of the reports involving a true medical error. For example, such systems capture medication incidents, of which some are purely undesirable patient reactions to proper medication use, some are due to errors in ordering or giving medication, and some are of unclear cause.

Despite the different development sources, the 2 reporting systems are actually quite similar. They share a common approach to capturing incidents regardless of the presence of error. Their